UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,615	12/30/2003	Arnold P. Nerenberg	NERE-3815	7492

5409 7590 07/25/2007

SCHMEISER, OLSEN & WATTS
22 CENTURY HILL DRIVE
SUITE 302
LATHAM, NY 12110

EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,615	NERENBERG, ARNOLD P.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application was filed December 30, 2003. Claims 1-57 are pending in this application and examined on the merits herein.

In view of the outcome of the pre-brief appeal conference on April 26, 2007, the rejection under 35 USC 112, first paragraph, of record in the previous office action, is withdrawn. The following new grounds of rejection are made:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 13, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (US patent 6368617, cited in PTO-892) Hastings et al. discloses a nutritional supplement for reversing many symptoms of aging, including restoring muscle mass, decreasing body fat, thickening skin and reducing wrinkles, increasing energy and sexual function, restoring the size of the pancreas, liver, heart, and other organs, improving vision and memory, elevating mood and improving sleep, normalizing blood pressure, increasing cardiac output and stamina, improving immune function, and assisting in wound healing. (column 2, lines 24-35) The supplement comprises a glycoamino acid complex, saccharides, a plant-derived source of L-dopa,

and L-alpha-glycerophosphoryl choline, among other ingredients. (column 2, lines 35-40) The glycoamino acid complex comprises L-glutamine, L-arginine pyroglutamate (L-arginine-2-pyrrolidine-5-carboxylate) and L-lysine hydrochloride, among other amino acids. (column 2, lines 45-50) The dietary supplement can be provided in liquid or powder form. (column 3, lines 13-15) A typical serving contains about 600-1900 mg of secretagogue, including glycoamino acid complex. (column 3, lines 32-33) Other ingredients that can be added include acetyl-L-carnitine, 60-190 mg. (column 4, lines 27-28, column 5, lines 10-24) One example is provided of a composition containing 1000 mg symbiotropin, 7227 mg maltodextrin, and 100 mg acetyl-L-carnitine. (column 6, lines 10-21) Hastings et al. does not exemplify a composition having the same range of each ingredient recited in instant claim 1 or a composition prepared as a tablet, wafer, or capsule.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the supplement composition of Hastings et al. having the specific amounts of L-glutamine, L-arginine pyroglutamate (L-arginine-2-pyrrolidine-5-carboxylate) L-lysine hydrochloride, and acetyl-L-carnitine recited in the instant claims, and to prepare the composition as a tablet, wafer, or capsule. One of ordinary skill in the art would have been motivated to prepare the composition in this manner because Hastings et al. already discloses a total of up to 1900 mg for all the amino acids together, and already discloses that the composition can be prepared in other oral dosage forms such as a liquid or powder. One of ordinary skill in the art would have reasonably expected success because optimizing the exact amounts of ingredients in a

known composition and the exact dosage form used to deliver a known product by a known route of administration represent ordinary and routine skill in the art, and furthermore, because the broad ranges (from 0.5-10g) recited in the instant claims allow a wide latitude in choosing the desired amount of each ingredient. In addition, the amount of each ingredient in a nutritional supplement is not critical so long as each ingredient is present in a reasonable amount, as none of the ingredients are harmful at or near the doses administered, and the level of each ingredient can be easily varied depending on the nutritional needs of the subject.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 1-5, 7-9, 11-13, 15-33, 35-37, 39-41, 43, 45-47, 49-51, and 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood. (US patent publication 20040071825, cited in PTO-892) Lockwood discloses a protein-rich nutritional supplement comprising approximately 13-100% edible nutritional food proteins, up to 57% edible carbohydrates, up to 78% edible amino acids, and up to 10% edible plant extracts. (p. 3, paragraph 0020) Although additional ingredients are recited (up to 10% edible fats, up to 15% edible vitamins and minerals, up to 4% chondroitin sulfate) All of these ingredients are presented in a range that comprises 0%, and are thus optional. This supplement is useful for various bodybuilding activities, as well as augmenting mental acuity and energy and supplementing nutritional intake, particularly protein, by administering the compound as a rapidly dissolving wafer or as agglomerated granules. (p. 4, paragraph 0031) The supplement is prepared as an

agglomerated granular composition (reasonably considered to be a powder) and can be dissolved in water to form a liquid composition. (p. 5, paragraph 0032) Edible nutritional food proteins include whey protein, and edible carbohydrates include maltodextrin and ribose. (p. 5, paragraph 0033) Edible amino acids include leucine, lysine, glutamine, pyroglutamic acid, taurine, arginine, tyrosine, and Acetyl-L-carnitine. (p. 5, paragraph 0035) Note that a combination of arginine and pyroglutamic acid is identical to the salt arginine pyroglutamate, also known as L-arginine-2-pyrrolidine-5-carboxylate. A preferred formulation contains 56-78% edible nutritional food proteins, 13-20% edible carbohydrates, less than 3% edible fats, 0-2% edible dietary vitamins and minerals, 0-27% edible amino acids, and 0-1% edible plant extracts. (p. 5, paragraphs 0039-0045) This formulation encompasses various embodiments of the claimed invention, such as one consisting of 20g whey protein (65% edible nutritional food protein) 5g of a combination of ribose and maltodextrin (14% edible carbohydrates) 1g each of L-lysine hydrochloride, acetyl-L-carnitine, L-leucine, L-tyrosine, taurine, and glutamine (19% edible amino acids) and 200mg lycopene (0.6% edible plant extract). These compositions do not contain steroids or hormones. Lockwood does not explicitly exemplify the amounts of active ingredients disclosed in the instant claims, nor a composition in the form of a tablet or capsule.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the supplement composition of Lockwood having the specific amounts of each ingredient recited in the instant claims, and to prepare the composition as a tablet or capsule. One of ordinary skill in the art would have been motivated to

prepare the composition in this manner because Lockwood already discloses a broad range including the claimed amounts of each ingredient, and already discloses that the composition can be prepared in other oral dosage forms such as a liquid, wafer, or powder. One of ordinary skill in the art would have reasonably expected success because optimizing the exact amounts of ingredients in a known composition and the exact dosage form used to deliver a known product by a known route of administration represent ordinary and routine skill in the art.

Furthermore, with regards to claims 43-52 in which the additional substance consists essentially of one particular ingredient, and 21-31, in which the composition consists essentially of L-arginine-2-pyrrolidone-5-carboxylate, lysine hydrochloride, and one of acetyl-L-carnitine and maltodextrin, according to MPEP 2144.04, omission of an element and Its function Is obvious If the function of the element Is not desired. Ex parte Wu , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) See also In re Larson, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) In the instant case, the prior art nutritional compositions described above are intended to supplement the diet of a bodybuilder or other subject in need of increased anabolic activity. The composition comprises a number of different components, such as proteins, amino acids, carbohydrates, and plant extracts that the subject may require more of in his or her diet. It would have been obvious for one of ordinary skill in the art to remove any ingredient or combination of ingredients from said composition depending on the specific nutritional status of the subject. For example, if the subject is obtaining enough calories and protein from his or her unsupplemented

diet, one of ordinary skill in the art could choose to omit the whey protein and carbohydrates, producing a composition comprised solely of various specific amino acids. In this case, the caloric and crude protein supplementing functions of the composition would be omitted with the omission of said ingredients.

Furthermore, the broad ranges (from 0.5-10g) recited in the instant claims allow a wide latitude in choosing the desired amount of each ingredient, overlapping the percentages recited by Lockwood. In addition, the amount of each ingredient in a nutritional supplement is not critical, so long as each ingredient is present in a reasonable amount, as none of the ingredients are harmful at or near the doses administered, and the level of each ingredient can be easily varied depending on the nutritional needs of the subject.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. as applied to claims 1-4, 13, and 16-20 above, and further in view of Schanze. (US patent 4426397, cited in PTO-892) The disclosure of Hastings is discussed above. Hastings does not disclose a composition additionally containing between 50 mg and 10g of bee pollen.

Schanze discloses compositions comprising a bee product such as bee pollen and a milk product, converted into a solid dietetic composition. (column 2, lines 24-36 and 52-57) These compositions can be used as a dietetic, anabolic, and strengthening aid for human beings and animals, as preparations for young children and sportsmen

and women or as a feed supplement for young animals. (column 3, lines 25-29) The milk product includes protein-enriched filtrates from milk, whey, or other byproducts of the milk industry. (column 3, lines 50-52) When the protein-enriched filtrate is produced from whey, it is reasonably considered to be whey protein.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the compositions of Schanze et al. containing bee pollen and whey protein to the compositions of Hastings et al. One of ordinary skill in the art would have been motivated to combine the two compositions because the compositions of Schanze are disclosed to be useful as an anabolic and strengthening aid, which is reasonably considered to be directed to the same purpose as the functions of the composition of Hastings et al. for restoring muscle mass and increasing energy. One of ordinary skill in the art would reasonably have expected success because combining two known compositions is well within the ordinary and routine level of skill in the art. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 6, 34, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood as applied to claims 1-5, 7-9, 11-13, 15-33, 35-37, 39-41, 43, 45-47, 49-

51, and 53-57 above, and further in view of Schanze. (US patent 4426397, cited in PTO-892) The disclosure of Lockwood is discussed above. Lockwood does not disclose a composition additionally containing between 50 mg and 10g of bee pollen.

Schanze discloses compositions comprising a bee product such as bee pollen and a milk product, converted into a solid dietetic composition. (column 2, lines 24-36 and 52-57) These compositions can be used as a dietetic, anabolic, and strengthening aid for human beings and animals, as preparations for young children and sportsmen and women or as a feed supplement for young animals. (column 3, lines 25-29) The milk product includes protein-enriched filtrates from milk, whey, or other byproducts of the milk industry. (column 3, lines 50-52) When the protein-enriched filtrate is produced from whey, it is reasonably considered to be whey protein.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the compositions of Schanze et al. containing bee pollen and whey protein to the compositions of Lockwood One of ordinary skill in the art would have been motivated to combine the two compositions because the compositions of Schanze are disclosed to be useful as an anabolic and strengthening aid, which is reasonably considered to be directed to the same purpose as the functions of the composition of Lockwood for supplementing the diet of bodybuilders to aid in various activities that involve strength and anabolic activity. One of ordinary skill in the art would reasonably have expected success because combining two known compositions is well within the ordinary and routine level of skill in the art. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be

useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. as applied to claims 1-4, 13, and 16-20 above, and further in view of Smeets et al. (US patent 6521591, cited in PTO-892) The disclosure of Hastings et al. is discussed above. Hastings et al. does not disclose a composition additionally containing between 500 mg and 10g of colostrum and 1-20g of whey protein.

Smeets et al. discloses the administration of an anabolism triggering component, a muscle biosynthesis substrate component, and a biosynthetic facilitator for enhancing muscular anabolism. (column 2, lines 1-29) The products can be prepared as powders or liquids. (column 2, lines 30-37) The initiator is a protein-rich food ingredient, particularly bovine colostrum. (column 2, lines 40-53) The substrate is a protein, particularly proteins rich in the essential amino acids leucine, lysine, and methionine, such as whey protein. (column 3, lines 38-48) It is also disclosed that bovine colostrum can act as a substrate as well as an initiator. The facilitator includes a carbohydrate, such as maltodextrin, and a krebs cycle precursor, such as glutamine. (column 4, lines 23-36)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the compositions of Smeets et al. containing bee pollen and whey

protein to the compositions of Hastings et al. One of ordinary skill in the art would have been motivated to combine the two compositions because the compositions of Smeets et al. are disclosed to be useful for enhancing muscular anabolism, which is reasonably considered to be directed to the same purpose as the functions of the composition of Hastings et al. for restoring muscle mass. One of ordinary skill in the art would reasonably have expected success because combining two known compositions is well within the ordinary and routine level of skill in the art. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 10, 38, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood as applied to claims 1-5, 7-9, 11-13, 15-33, 35-37, 39-41, 43, 45-47, 49-51, and 53-57 above, and further in view of Smeets et al. (US patent 6521591, cited in PTO-892) The disclosure of Lockwood is discussed above. Lockwood does not disclose a composition additionally containing between 500 mg and 10g of colostrum and 1-20g of whey protein.

Smeets et al. discloses the administration of an anabolism triggering component, a muscle biosynthesis substrate component, and a biosynthetic facilitator for enhancing muscular anabolism. (column 2, lines 1-29) The products can be prepared as powders

or liquids. (column 2, lines 30-37) The initiator is a protein-rich food ingredient, particularly bovine colostrum. (column 2, lines 40-53) The substrate is a protein, particularly proteins rich in the essential amino acids leucine, lysine, and methionine, such as whey protein. (column 3, lines 38-48) It is also disclosed that bovine colostrum can act as a substrate as well as an initiator. The facilitator includes a carbohydrate, such as maltodextrin, and possibly a krebs cycle precursor, such as glutamine. (column 4, lines 23-36)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the compositions of Smeets et al. containing bee pollen and whey protein to the compositions of Lockwood One of ordinary skill in the art would have been motivated to combine the two compositions because the compositions of Smeets et al. are disclosed to be useful for enhancing muscular anabolism, which is reasonably considered to be directed to the same purpose as the functions of the composition of Lockwood for supplementing the diet of bodybuilders to aid in various activities that involve strength and anabolic activity. One of ordinary skill in the art would reasonably have expected success because combining two known compositions is well within the ordinary and routine level of skill in the art. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. as applied to claims 1-4, 13, and 16-20 above, and further in view of Pras et al. (Reference included with PTO-892) The disclosure of Hastings et al. is discussed above. Hastings et al. does not disclose a composition comprising Macuna pruriens.

Pras et al. discloses that L-dopa occurs in various *Mucuna* species (p. 263, paragraph 1) and in particular has been isolated from cell cultures of *Mucuna pruriens*. (p. 263, paragraph 2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add an extract of *Mucuna pruriens* containing L-dopa to the compositions of Hastings et al. One of ordinary skill in the art would have been motivated to add this ingredient to the composition because Hastings et al. already discloses that the composition can contain a plant-derived source of L-dopa, and *Mucuna pruriens* is known to contain L-dopa. One of ordinary skill in the art would have reasonably expected success because adding an additional ingredient to an existing formulation is within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 14, 42, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood as applied to claim1-5, 7-9, 11-13, 15-33, 35-37, 39-41, 43, 45-47, 49-51, and 53-57 above, and further in view of Ceda et al. (Reference

included with PTO-892) The disclosure of Lockwood is discussed above. Lockwood does not disclose a composition comprising alpha-glycerophosphorylcholine.

Ceda et al. discloses a study in which alpha-glycerophosphorylcholine (alpha-GPC) is administered to young and elderly patients in an amount of 1g. (p. 119, right column, paragraph 3) Alpha-GPC was seen to cause an increase in growth hormone (GH) levels either alone or in combination with GHRH. (p. 120, left column, first paragraph and figure 1)

It would have been obvious to one of ordinary skill in the art to add alpha-GPC to the composition of Lockwood. One of ordinary skill in the art would have been motivated to add this ingredient because Ceda et al. discloses that alpha-GPC increases growth hormone levels, which is reasonably expected to improve the anabolic effect of the composition of Lockwood. One of ordinary skill in the art would have reasonably expected success because adding an additional ingredient to an existing formulation is within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 1, 2, 15-21, 24, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Simone (US patent 6380252, cited in PTO-892) in view of Isidori et al. (Reference of record in previous office action) De Simone discloses a therapeutic use of L-acetylcarnitine for increasing the levels of IGF-1. (column 1, lines 15-34) This therapy is useful for treating a wide range of disorders. (column 1, lines 52-67) In one

embodiment, the active agent is administered in combination with other active agents, including growth hormones. (column 3, lines 45-53) In one embodiment, 0.1-10g of L-acetylcarnitine are administered per day. (column 4, lines 37-38) In example 1, patients are administered 3g/day of L-acetylcarnitine. (column 5, lines 33-40) De Simone does not disclose a composition comprising 1-10g acetyl-L-carnitine and further comprising 0.5-10g of L-arginine-2-pyrrolidone-5-carboxylate and 0.5-10g lysine hydrochloride. De Simone does not disclose these pharmaceutical dosage forms as powders, tablets, liquids, wafers, or capsules.

Isidori et al. discloses a study in which patients were administered orally 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride. (p. 475, last paragraph) The subjects demonstrated increased growth hormone levels in the hours following this treatment. (p. 476, table I, 477, table II, paragraphs 1-2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride to the pharmaceutical compositions of De Simone and to formulate these pharmaceutical compositions as powders, tablets, liquids, wafers, or capsules. One of ordinary skill in the art would have been motivated to combine the two compositions because De Simone already discloses that L-acetylcarnitine can be administered in combination with growth hormone, and Isidori et al. discloses that the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride causes an increase in growth hormone, effectively administering growth hormone. One of ordinary skill in the art would reasonably have expected success because combining

known compositions and administering them in conventional oral dosage forms in well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 3, 4, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Simone (US patent 6380252, cited in PTO-892) in view of Isidori et al. (Reference of record in previous office action) as applied to claims 1, 2, 15-21, 24, 27-31 and 24 above, and further in view of Kanig (US patent 3873694, cited in PTO-892) The disclosure of De Simone in view of Isidori et al. is discussed above. De Simone in view of Isidori et al. does not disclose a composition comprising maltodextrin.

Kanig discloses a direct compression tableting composition comprising a crystalline sugar and a maltodextrin. (column 4, lines 1-8) The compressed tablets contain from 15-35% of maltodextrin and have an exceptionally high active ingredient carrying capacity. (column 4, lines 23-45) All active ingredients compatible with the compression ingredients can be tableted in this manner. (column 8, lines 15-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the aforementioned composition of De Simone in view of Isidori et al. in a tablet according to Kanig. One of ordinary skill in the art would have been motivated to prepare the composition in this manner because Kanig discloses that these tablets can be used with a wide range of active ingredients. One of ordinary skill in the art would reasonably have expected success because preparing a conventional dosage

form such as a tablet, that is known in the prior art, with a known active agent, is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 1, 3, 17, 21-23, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (US patent publication 2002/0156019, cited in PTO-892) in view of Isidori et al. (Of record in previous office action) in view of Kanig (US patent 3873694, cited in PTO-892) Foster discloses a method of treating a human subject with a substantially pre composition of human growth hormone that lacks other hormones. (p. 1, paragraphs 0009-0011) The subject is a patient over 40 years old suffering from age-related decline in HGH levels. (pp. 1-2, paragraphs 0012-0013) Foster does not disclose a method comprising administering 0.5-10g of L-arginine-2-pyrrolidone-5-carboxylate, 0.5-10g of L-lysine hydrochloride, and 1-10g of maltodextrin, or a tablet comprising these ingredients.

Isidori et al. discloses a study in which patients were administered orally 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride. (p. 475, last paragraph) The subjects demonstrated increased growth hormone levels in the hours following this treatment. (p. 476, table I, 477, table II, paragraphs 1-2)

Kanig discloses a direct compression tableting composition comprising a crystalline sugar and a maltodextrin. (column 4, lines 1-8) The compressed tablets contain from 15-35% of maltodextrin and have an exceptionally high active ingredient

carrying capacity. (column 4, lines 23-45) All active ingredients compatible with the compression ingredients can be tableted in this manner. (column 8, lines 15-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer a composition of 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride to a patient suffering from age-related decline in HGH levels as described by Foster. One of ordinary skill in the art would have been motivated to do this because foster already discloses that exogenous growth hormone replacement is useful for treating this condition, and Isidori et al. discloses that the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride causes an increase in growth hormone, effectively administering growth hormone. One of ordinary skill in the art would reasonably have expected success because Isidori et al. already discloses that this composition increases growth hormone levels.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the aforementioned composition of Foster in view of Isidori et al. in a tablet according to Kanig. One of ordinary skill in the art would have been motivated to prepare the composition in this manner because Kanig discloses that these tablets can be used with a wide range of active ingredients. One of ordinary skill in the art would reasonably have expected success because preparing a conventional dosage form such as a tablet, that is known in the prior art, with a known active agent, is well within the ordinary and routine level of skill in the art.

With regard to the specific amounts of each ingredient recited in instant claim 23, 1200 mg is reasonably considered to be "about 1.5g" and it is expected that one of ordinary skill in the art would be motivated to select the embodiment containing 3g of maltodextrin from the broader teaching of Kanig because a tablet containing 50% maltodextrin (e.g. 2.4g active ingredients, 3g maltodextrin, 3g crystalline sugar, ~35% maltodextrin) is within the range of embodiments (15-35% maltodextrin) disclosed by Kanig.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 1, 3, 17, 21-23, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chein (US patent publi6187750, cited in PTO-892) in view of Isidori et al. (Of record in previous office action) in view of Kanig (US patent 3873694, cited in PTO-892) Chein discloses a method of treating symptoms consistent with multiple sclerosis, comprising administering HGH in doses of less than 0.5 mg per day. (column 2, lines 13-20) Chein does not disclose a method comprising administering 0.5-10g of L-arginine-2-pyrrolidone-5-carboxylate, 0.5-10g of L-lysine hydrochloride, and 1-10g of maltodextrin, or a tablet comprising these ingredients.

Isidori et al. discloses a study in which patients were administered orally 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride. (p. 475, last paragraph) The subjects demonstrated increased growth hormone levels in the hours following this treatment. (p. 476, table I, 477, table II, paragraphs 1-2)

Kanig discloses a direct compression tableting composition comprising a crystalline sugar and a maltodextrin. (column 4, lines 1-8) The compressed tablets contain from 15-35% of maltodextrin and have an exceptionally high active ingredient carrying capacity. (column 4, lines 23-45) All active ingredients compatible with the compression ingredients can be tableted in this manner. (column 8, lines 15-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer a composition of 1200 mg of L-arginine-2-pyrrolidone-5-carboxylate and 1200 mg of L-lysine hydrochloride to a patient suffering from symptoms consistent with multiple sclerosis as described by Chein. One of ordinary skill in the art would have been motivated to do this because foster already discloses that exogenous growth hormone replacement is useful for treating this condition, and Isidori et al. discloses that the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride causes an increase in growth hormone, effectively administering growth hormone. One of ordinary skill in the art would reasonably have expected success because Isidori et al. already discloses that this composition increases growth hormone levels.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the aforementioned composition of Foster in view of Isidori et al. in a tablet according to Kanig. One of ordinary skill in the art would have been motivated to prepare the composition in this manner because Kanig discloses that these tablets can be used with a wide range of active ingredients. One of ordinary skill in the art would reasonably have expected success because preparing a conventional dosage

form such as a tablet, that is known in the prior art, with a known active agent, is well within the ordinary and routine level of skill in the art.

With regard to the specific amounts of each ingredient recited in instant claim 23, 1200 mg is reasonably considered to be "about 1.5g" and it is expected that one of ordinary skill in the art would be motivated to select the embodiment containing 3g of maltodextrin from the broader teaching of Kanig because a tablet containing 50% maltodextrin (e.g. 2.4g active ingredients, 3g maltodextrin, 3g crystalline sugar, ~35% maltodextrin) is within the range of embodiments (15-35% maltodextrin) disclosed by Kanig.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson
Patent Examiner
AU 1623
7/18/07

Anna Jiang
7/19/07
Supervisory Patent Examiner
AU 1623